

**UNIVERSITY OF WASHINGTON
CONSENT FORM
KING COUNTY PUBLIC HEALTH**

Consent Form

HomeBASE: Asthma Support and Education for Adults

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**In the event of a medical emergency, call Harborview Hospital: 206-731-5865.
Available 24 hours a day.**

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

You are being asked to take part in a research study. It is up to you if you want to take part.

The purpose of this research study is to improve the health of adults who have asthma. In this study a community health worker will visit you at home to show you how to monitor

and control your asthma symptoms and help to identify things that may make the your asthma worse. They will also work with you to make the home safer and will provide supplies to help you keep your home healthy (vacuum cleaners, mattress and pillow covers, HEPA air filters (as needed), and cleaning supplies).

The study will compare home visits to usual care. Usual care is the kinds of instructions, appointments, and information you get from your healthcare provider. You will be assigned by chance (like the flip of a coin) to see which group you will be in (Group A or Group B). The first group is the usual care that a person gets from his/her regular medical care provider. The second is the regular care plus the community health worker home visits.

We expect that all adults who take part in this study will benefit directly. Taking part in the study may also benefit other adults in the future who have asthma. We hope the information gained from this study will help find new ways to provide better asthma education and care for adults who have asthma.

We expect about 420 adults who live in the King County area will take part in this study. The study will last one year. Adults who have mild to severe asthma will be asked to take part.

STUDY PROCEDURES

Enrolling in the Project

Project staff has confirmed with your medical provider that you have asthma and are eligible to take part in this study. You will be asked questions about your home life and medical condition. You may refuse to answer any questions or items in any test our questionnaire, inventory or interview. This will not keep you from participating in the study.

Before enrolling in the study, you will be asked to complete an enrollment interview. The interview will take place in your home. **APPROVED**

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This appointment will last about 2 ½ hours, and include these things:

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- Questions about your asthma (symptoms, how asthma affects your life, and what medicines you use), other medications such as beta-blockers and use of tricyclic antidepressants. If you use these medications, you will not be able to have the allergy skin test which is done at the University of Washington's General Clinical Research Center (GCRC).
- You will be asked to blow into a small machine (spirometer) to measure your breathing. If you would prefer to have this test done in a medical center, the community health worker will make an appointment for you to have the test done at the GCRC. The test will still be performed by the community health worker. The results of this test will be given to your health care provider to put into your records.

The community health worker will walk around your home with you to look for things such as mold or pests that might make your asthma worse, and ask you about things you might do to get rid of things that can set off asthma.

- During the home walk around, staff may take pictures to document housing conditions (not to include people). Pictures will be used for training purposes, and to describe the

project. If you do not want pictures to be taken, you are free to say so and we will NOT take your picture.

- At the end of the in-home enrollment visit, the community health worker will make an appointment for you to go to the GCRC for allergy skin testing. To help you make this visit, they study will help pay for your travel cost.

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Allergy Test Visit

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This appointment will last about 1 hour, and include these things:

- Re-ask questions about medications such as beta-blockers and use of tricyclic antidepressants. If you use these medications, you will not be able to have the allergy skin test.
- Women of child bearing years will be screened again for pregnancy and may be give a urine pregnancy test. If you are pregnant, you will not be able to have the allergy skin test.
- You will receive a free allergy skin test. Skin tests consist of 17 slight scratches of the skin. The skin tests can help us learn what things you are allergic to. You will be told the results of your tests immediately. Results will be given to your doctor, because this may help your doctor take better care of your asthma. Knowing what you are allergic to may help you to better control your asthma. If you have received an allergy skin test within the past 6 months, you may choose not to take the test again. We will ask for your signed permission to obtain the results of your allergy skin test from the doctor or clinic that performed the test.

The study will last for one year, though you are free to withdraw at anytime. During the year, you will receive home visits and phone calls by a project community worker. Also, you will be contacted by phone 6 months from enrollment by project staff to answer questions about your asthma. It will take about 15 minutes for the call.

Group A

If you are in this group, you will receive one assessment home visit and up to four follow-up home visits from a project community health worker during the study. This person will work with you to develop a plan to that will help you control your asthma better and encourage you to actively carry out the plan. Following this plan may take a couple of hours or more of your time each week. The project worker will bring you information to help you with your plan. You will receive the special tools that may make your home healthier, including a vacuum cleaner, HEPA filter (if appropriate) and cleaning supplies (bucket, vinegar, baking soda, and scouring pad) free of charge. You will receive all of your supplies by the fourth follow-up visit. It might be useful to make some home improvements and, if you would like, we can help you contact your landlord about them. Each visit will last about an hour.

Group B

If you are in this group you will receive one in-home check visit from a project community health worker. A final visit will occur at 12 months. After the year is over and you have completed; the In-home check and Exit Interview, (which is described below), you will receive the study services from the Community Health Worker. The services include working with you to develop a plan to control your asthma better. During this visit, you will receive the special tools that may make your home healthier, including a vacuum cleaner, HEPA filter (if appropriate) and cleaning supplies (bucket,

vinegar, baking soda, and scouring pad) free of charge. This visit will take about 2 hours.

Completing the Project

The research project will be over after you complete the Exit Interview and the In-Home Check Up. These will take place a year from the time you enrolled.

Exit Interview and In-Home Check Up

A project community health worker will come to your home to complete an Exit Interview, In-Home Check Up and a spirometry test at the end of your year in the study similar to the one during enrollment. If you would like to have the spirometry test done in a medical center, the community health worker will make an appointment for you to have the test done at the GCRC. The test will still be performed by the community health worker. This visit will take about 1 and ½ hours. We will also measure the moisture level in the air in your house.

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RISKS, STRESS, OR DISCOMFORT

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Interviews

You may find some of the questions asked during the interview to be embarrassing. For example we will ask you how often you clean your home and whether you had any problems with cockroaches. You are free to not answer any of the questions.

Allergy Skin Testing

There may be some discomfort and itching with this test but it shouldn't last long. Severe allergic reactions are very rare (less than one in a million). A doctor or a nurse will be in the clinic when the tests are being done. You can still take part in the study if you don't want to have the allergy testing.

Pest Control

If you have problems with roaches, the community health worker will help you by placing a gel with roach bait in places where roaches might be found but where children can't get to it. The gel contains a chemical (pesticide) that kills roaches but can harm people if they eat large amounts of it or get it on the skin or eyes. Only small amounts will be used in your home. If you don't want to use the bait, you don't have to and can still take part in the study.

Spirometry

You will be asked to do a spirometry test which requires blowing out as hard and as long as you can into a small machine. This may cause you to briefly feel dizzy or light headed or may cause you to cough. Very rarely it may cause fainting.

Landlords

Your landlord might not respond well to a request to make changes in your home. We will help you if this should happen. It is possible the landlord could take action against you. If this occurs, project staff, along with Columbia Legal Services and/or the Seattle Tenants

Union, will be available to assist you. Note: in an earlier and similar study, there were *no* cases of landlords taking action against participants.

Other Considerations

If project staff sees clear signs of child abuse or neglect and/or vulnerable adult abuse or neglect, they are required by law to report this to Child Protective Services or Adult Protective Service.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to participate, you can continue to use your regular healthcare provider.

BENEFITS OF THE STUDY

Adults participating in the study may have a number of benefits. These benefits might include increased asthma self-management skills, asthma control support, and supplies that may make your home healthier. Both groups will receive these benefits

If this project shows that home visits improve asthma control, this project can be used to help community healthcare providers and other asthma programs promote access to home visits for all adults with asthma. Society will benefit from improved health of its members and potentially decreased costs for caring for people with asthma.

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OTHER INFORMATION

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Taking part in research is voluntary. You may choose not to take part and may withdraw from the study at any time, without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect the care that you or receive. All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Participation will be kept confidential, within the limits of the law. A copy of this signed consent form will be put into your participant file. Your name will be separated from any information collected about you and your house. No names or other identifying information will be used in any publications or presentations that may result from this study. Access to study data that identifies participants will be limited to the project, your medical provider, and the funding agency, the National Institute of Environmental Health Sciences (NIEHS). Data from individuals (such as questionnaires) will be kept until December 2017.

This project is funded by the National Institute of Environmental Health Sciences. The allergy testing and other study procedures will be done at no cost to you. You will be paid for completing each of the study visits and procedures:

Enrollment Interview:	\$35 Safeway gift card
Phone Interview at 6 months: interview	\$10 gift card after completing the

Exit interview at year 1:

\$50 Safeway Gift Card

Total:

\$95.00

Your travel costs that may result from making the study visit to the University of Washington will also be reimbursed. You will also receive the following equipment free of charge as a result of taking part in the study: a vacuum cleaner, cleaning supplies, allergy control mattress covers and pillow covers, and HEPA filters (if appropriate). You will receive the allergy control covers at your first meeting with the project worker. Those in Group A will receive the other supplies at in-home visits during their year in the project. Group B will receive them at their home visit after completing the one year project.

In the event of a physical injury as a direct result of participating in this study, medical care at routine cost will be available to you. The University of Washington will pay up to \$10,000 to treat injury or illness caused by the study. No other compensation is available. Public Health Seattle King County does not have a program for monetary or other forms of compensation for research-related injury.

If any problems or questions come up while taking part in the study, you can call Miriam Philby, Project Manager, at the Public Health – King County. Her phone number is 206-263-8235.

For questions about your rights as a research participant, contact the University of Washington Institutional Review Board (IRB) at (206) 543-0098. The IRB is a committee that reviews the research to be sure that your rights as a research participant are protected

Printed name of study staff obtaining consent	Signature	Date
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Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date
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When subject is not able to provide informed consent

Printed name of representative	Signature of representative	Date
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Relationship of representative to subject

Copies to: Researcher
 Subject
 Subject's Participant Record

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